CAREER OPPORTUNITY

DESCRIPTION

ORGANIZATION: Africa Clinical Research Management Ltd (ACE Research)

POSITION TITLE: Clinical Research Associate I -Trainee

JOB: Clinical Research Monitoring

DEPARTMENT: Clinical Operations

WORKSITE: Sierra Leone

REPORTS TO: Head of Clinical Operations

PURPOSE

Engage in ACE Research training program to gain knowledge and skills required to independently conduct clinical monitoring visits in accordance with study protocol, standard operating procedures, international conference on harmonization (ICH) good clinical practice (GCP), and applicable regulatory requirements.

This is a trainee position, available immediately and open exclusively for citizens of the Republic of Sierra Leone. To be eligible to apply, candidates must be citizens and domiciled in the Republic of Sierra Leone.

ESSENTIAL FUNCTIONS/JOB RESPONSIBILITIES:

- Complete appropriate therapeutic, protocol and clinical research training to perform job duties.
- Gain experience in study procedures by working with experienced clinical staff including: Clinical Research Associates (CRAs), Project Specialists (CTA), Project Managers and other members of the project team such as data management.
- Under close supervision, perform site selection, initiation, monitoring and close out visits in accordance with contracted scope of work and good clinical practices.
- Under close supervision, administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues.
- Under close supervision, evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to ICH-GCP and applicable regulations. Escalate quality issues to CRAs and/or Head of Clinical Operations.
- Under close supervision, manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, source document verification, case report form (CRF) completion and submission, and data query generation and resolution.

- Under close supervision, create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required study documentation.
- Under close supervision, assists in the development of associated study documents (Safety Monitoring Plans, Manual of Operations and Informed Consents).
- Under close supervision, ensure that adverse events, concomitant medications, and inter-current illnesses are reported in accordance with the protocol on the CRF.
- Under supervision, assist with setup, quality and maintenance of the Trial Master Files (TMF) in accordance with SOPs, Good Clinical Practice (GCP), ICH guidelines and other regulations.
- Participate in project team meetings.
- Maintains a safe workplace ensuring that he/she is aware of and observes appropriate safety and occupational health rules and regulations. Employee is required to attend safety training and report any infractions of safety procedures to the facility Safety Officer.
- Perform other duties as required and assigned.

QUALIFICATIONS

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

1. Bachelor's degree or equivalent in clinical, health, or life science or professional healthcare discipline.
2. Minimum of 1 year of related clinical research education, training and experience is desirable.
3. Knowledge of applicable clinical research regulatory requirements i.e. ICH GCP Guidelines, country/regional guidelines is desirable.
4. Computer skills including proficiency in use of Microsoft Word, Excel and PowerPoint and use of a laptop computer.
5. Strong written and verbal communication skills including good command of English language.
6. Excellent organizational and problem-solving skills.
7. Effective time management skills and ability to prioritize.
8. Ability to establish and maintain effective working relationships with coworkers, managers and clients.
9. Ability to travel 50% both locally and/or internationally.

All applications should be submitted by e-mail through careers@aceresearchafrica.com by 30th May 2018

ACE RESEARCH
Advancing Global Health Research

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